MINISTRY OF LAW, JUSTICE AND COMPANY AFFAIRS
(DEPARTMENT OF COMPANY AFFAIRS)
New Delhi, the 14th March 1974
COST ACCOUNTING RECORDS (BULK DRUGS) RULES, 1974
(As amended up to 31.10.1997)

G.S.R. 130(E).- In exercise of the powers conferred by sub-section (1) of Section 642, read with clause (d) of sub-section 209, of the companies Act, 1956 (1 of 1956), the Central Government hereby makes the following rules, namely:

1. Short Title and Commencement

(1) These rules may be called the Cost Accounting Records (Bulk Drugs) Rules, 1974.
(2) They shall come into force on the 1st day of April, 1974.

2. [Application

They shall apply to every company engaged in the production, processing or manufacturing of bulk drugs under any system of medicine including Ayurvedic, Homeopathic, Siddha and Unani systems of medicine and intermediates thereof excepting those companies falling under the category of Small Scale Industrial Undertaking.] [1]

Explanation - For the purpose of this rule, the expression 'Small Scale Industrial Undertakings' means a company-

[(a) The aggregate value of the machinery and plant installed where in dose not exceed the limit as specified for a small scale industrial undertaking under the industries (Development and Regulation Act 1951 (65 of 1951), as on the last date of the presenting financial year.][2]

[(b) The aggregate value of the realization made by the company from the sale or supply of all its products during the preceding financial year does not exceed ten crore rupees.][3]

3. Definitions

In these rules, unless the context otherwise requires,-

(a) The expressions "bulk drug", "essential bulk drug" and "formulation" .shall have the meaning respectively assigned to them in the Drugs (Prices Control) Order, 1970 as amended from time to time;
(b) "Intermediate" means any compound which is manufactured from primary or basic raw material and which is used in the production, processing or manufacture of any bulk drug.

4. Maintenance of Records

(1) Every company to which these rules apply shall, in respect of each of its financial year commencing on or after the commencement of [till the 31st day of March, 2002 or the close of the relevant financial year in 2002] [4] these rules, keep proper books of account containing inter-alia the particulars specified in Schedules I and II annexed to these rules relating to the utilisation of materials, labour and other items of cost so far as they are applicable to the bulk drugs and/or intermediates.

Provided that if the said company is manufacturing any products or engaged in other activities in addition to any of the bulk drugs, and/or intermediates the particulars relating to the utilisation of materials, labour and other items of cost in so far as they are applicable to such other products of activities shall not be included in the cost of such bulk drug and/or intermediate.

(2) The books of accounts referred to in sub-rule (1) shall be kept on a regular basis so as to make it possible to calculate the cost of production and cost of sales of each of the bulk drugs and/or intermediates at regular intervals, say quarterly during the financial year (hereinafter referred to as the relevant period) as well as for the financial year

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[1]. Substituted by G.S.R. 707(E) dated 28th September 2001.
[2]. Inserted by G.S.R. 437(E) dated 3rd August1998.
[3]. Inserted by G.S.R 311(E) dated 24th March1993
[4]. Inserted by G.S.R. 707(E) dated 28th September 2001

as a whole from the particulars entered therein and every such books of accounts and the proforma specified in Schedule II shall be completed within ninety days from the end of the financial year of the company to which they relate.

[(2A) Every company to which these rules apply shall, in respect of each of its financial year commencing on or after the 1st day of April, 2002 keep proper books of account relating to utilization of materials, labour and other items of cost insofar as they are related to the production or manufacture or processing of Bulk Drugs. The books of account, so maintained shall contain, inter alia, the particulars specified in Schedule III annexed to these rules and Proformae A, B, C, and D mentioned in the said Schedule:

Provided that if the said company is manufacturing any other product(s) or is engaged in other activities in addition to manufacture of product under reference, the particulars relating to utilization of materials, labour and other items of cost in so far as they are related to the manufacture of such other products or activities shall not be included in the determination of cost of Bulk Drugs referred to in rule 2.

(2B) The books of account referred to in sub-rule (2A) shall be kept on a regular basis in such a manner as to make it possible to calculate the cost of production and cost of sales of each type of Bulk Drugs produced, processed or manufactured for every financial year from the particulars entered therein. Every such book of account and the Proforma specified in the said Schedule III shall be completed not later than ninety days from the close of the financial year of the company to 'which it relates.

(2C) The statistical and other records shall be maintained in accordance with the provisions of the Schedule III, which shall be such as to enable the company to exercise, as far as possible. Control over the various operations and costs with a view to achieve optimum economies In cost These records shall also provide the necessary data required by the Cost Auditor to suitably report on all the points referred to in the Cost Audit (Report) Rules, 1996.]**[5]**

(3) It shall be the duty of every person referred to in sub-section (6) and sub-section (7) of Section 209 of the Companies Act, 1956 (1 of 1956) to take all reasonable steps to secure compliance by the company with the [provisions of sub-rules (1), (2), (2A), (2B) and (2C)][6] in the same manner as they are liable to maintain financial accounts required under sub-section (1) of Section 209 of the said Act.

5. Penalty

If a company contravenes the provisions of rule 4, the company and every officer thereof who is in default, including the persons referred to in sub-rule (3) of that rule [shall subject to the provisions of section 209 of the Companies Act, 1956 (1 of 1956) be punishable] [7] with fine which may extend to five hundred rupees and, where the contravention is a continuing one, with a further fine which may extend to fifty rupees for every day after the first during which such contravention continues.

[5, 6] Inserted by G.S.R. 707(E) dated 28th September 2001

[7]. Inserted by G.S.R. 789 dated 3rd June 1977

SCHEDULE I

(See Rule 4)

1. Production Materials

(a) Adequate records shall be maintained showing receipts, issues and balances both in quantities and cost of each item of raw material and intermediate required and actually used for producing, processing or manufacturing any bulk drug and/or intermediate. The basis on which the said quantities and costs have been calculated shall be clearly indicated in the cost records, or, if so desired by the company, in a separate manual of procedure, if any, maintained by the company or in foot notes or explanatory notes to the cost statements. The basis adopted shall be applied consistently. The costs shown in the records shall include all direct charges up to the works. Any wastage whether in storage, transit or for other reasons of these materials shall be shown separately and the method of dealing with such losses in costs shall also be disclosed in the cost records.

Adequate records showing the consumption of each item of raw material for production shall be maintained. If the quantity and cost of materials consumed are determined on any basis other than actuals, the method adopted shall be mentioned in the cost records. The overall reconciliation of such costs of materials with the actuals shall be made periodically and in any case at the end of the relevant period, explaining the reasons for variances. The method followed for adjusting the cost variances in determining the actual costs of the bulk drugs and/or intermediates shall be clearly indicated in the cost records.

(b) Where basic raw materials or ingredients, such as Sorbitol for the manufacture of Vitamin 'C; or for other bulk drugs and/or intermediates and manufactured by the company or by its holding company or its wholly owned subsidiary, adequate records showing the cost of production of such items shall be maintained in such details as may enable the company to fill up the particulars in Proforma 'A' of Schedule II or in any form as near thereto as practicable. Where farm products are raised by the company for use in the manufacture of bulk drugs and/or intermediates or phytochemical products, adequate records to disclose the cost of production of such products shall be maintained in a suitable form. Separate cost statements in respect of each such raw material/ingredient/farm product shall be maintained by the company. The records of these materials shall be maintained in such details as may enable of the company to determine the actual cost of production as well as the ultimate cost at the consuming point including all charges upto the works. The basis of pricing adopted by the holding company or subsidiary company for the supply of these raw materials to the subsidiary or holding company, as the case may be, shall be disclosed in the cost records. .

(c) Adequate quantitative records for determining the net consumption of solvents like acetone, alcohol, methanol which are used for processing shall be maintained. The cost records shall clearly indicate absorption or loss in the process of solvents used for the production of each bulk drug and/or intermediate in a scientific manner indication in-plant stocks and actual recovery of pure solvents arising out of production of each individual bulk drug and/or intermediate Adequate records shall also be maintained showing the receipts, issues and balances, both in quantities and costs of process chemicals such as caustic soda, activated carbon and benzene.

(d) The records relating to consumption of production materials shall, as far as possible, be identified with the batch of production or the cost centres to which the materials are issued.

II. Consumable stores, small tools, machinery spares etc.

(a) Adequate records shall be maintained to show all receipts, issues and balances both in quantity and cost of each item of consumable stores, lubricants and items of spare parts and consumable tools required in connection with the manufacture of the bulk drug and! or intermediate. The costs shown shall include all direct charges upto works, wherever specifically incurred. In the case of small tools, the costs of which are insignificant, the company may, if it so desires, maintain such records for the main group of such items.

(b) The cost of consumable stores, small tools and machinery spars consumed shall be charged to the relevant heads of account such as repairs to plant and machinery, repairs to buildings, maintenance of town-ship and maintenance of vehicles. Items issued for capital works, such as additions to buildings, plant and machinery, shall be shown under the relevant capital heads. Any wastage in storage, transit or for other reasons shall be shown separately. The method of dealing with such losses in costs shall also be indicated in the cost records.

III. Power and Fuel

Adequate records shall be maintained in order to ascertain the cost of power and fuel. The cost of power and fuel consumed shall be determined on the basis of actual meter reading of consumption or calculated on a reasonable basis and applied consistently. Where power is generated by the company itself, separate records shall be maintained to show in detail the different items making up the cost of generation of power.

IV. Steam

Adequate records shall be maintained to ascertain the total quantity and cost of steam generated and the quantity and cost of steam consumed in the different processes, departments or cost centres including that consumed for generation of power. The cost of steam so consumed shall be calculated on a reasonable basis and applied consistently.

V. Brine and Chilled water

Adequate records shall be maintained to determine correctly the quantity and the cost of brine and chilled water utilised by the different production departments.

VI. Raw water, Soft water, Demineralised water, compressed air

Adequate records showing the cost of production and distribution of raw water, soft water, demineralised water and compressed air shall be kept. The cost of these services shall be charged to the respective production departments and to the products on a reasonable basis.

VII. By-products

Adequate records shall be maintained showing the quantity of by-products derived and the basis adopted for their pricing for giving credit to the respective bulk drugs and intermediates. The basis so adopted for pricing the by-products shall be equitable and consistent. Records showing the expenses incurred on the recovery of the by-products like operation of the distillation columns and treatment plant, shall be kept to ascertain correctly the ultimate cost of the by-products in saleable form. Records showing the actual quantity sold and sales realisation of the by-products shall also he maintained.

VIII. Wages and Salaries

(a) Proper and systematic records shall be maintained to show the attendance and the earnings of workers and other operational staff indicating the departments or the work on which they are employed. Where payments to workers are made on piece-rate basis the records relating thereto shall be maintained so as to enable proper assessment of wages payable to such workers. Necessary records shall also be maintained in respect of all payments made for overtime work and to casual labour. Where any incentive payments are made, whether in the shape of production bonus or other forms of incentive based on output achieved by the workers individually or collectively, proper records shall also be maintained for the assessment of such payments.

(b) The records shall further show the wages and salaries relating to various manufacturing and other departments or units or cost centres, being the amounts payable and allocated to the different departments or units or cost centres. Idle time of workers shall be recorded separately, indicating the reasons for such idle time and the method of its treatment in calculation the costs of products. Any wages and salaries incurred towards additions to plant, machinery, buildings or other fixed assets shall be allocated to the relevant capital heads in the accounts.

(c) If the wages and salaries are allocated to the departments or units or cost centres or products on any basis other than acutals, the reconciliation of such wages with actuals and method followed for adjusting the cost variances, if any, in determining the actual cost of bulk drugs and/or intermediates shall be indicated in the cost records.

IX. Service Department expenses

Expenses of service departments shall be apportioned to other service departments and the production departments on the basis of services rendered. Detailed records about the utilisation of the services by the different departments, cost centres and their absorption in product costs shall be maintained.

X. Multi-purpose vessels

When more than one manufacturing process is carried out in a particular or series of vessels, adequate records about the usage of such vessels for different products on an equitable basis such as equipment occupancy hours. Where composite machine hour rates are applied for absorption of wages, overheads and equipment usage, proper records relating to the utilisation of labour and multi-purpose vessels for different process connected with the manufacture of different products shall be kept to enable determination of total machine hours and the amounts chargeable to the respective bulk drugs and or intermediates. The variances between the actuals and the amounts charged at pre-determined rates shall be adjusted for arriving at the actual cost of production at the end of the year.

XI. Workshop/Repairs and Maintenance Shop expenses.

Adequate records showing the expenditure incurred in the workshop and in the repairs and maintenance shop shall be maintained. The records shall further indicate the basis of charging the expenditure incurred in these shops to the different departments or manufacturing units or cost centres. Expenditure on a major repair work from which benefit is likely to accrue for more than one financial year, shall be shown separately in the cost records, indicating the method of its treatment in determining the cost of bulk drugs and/or intermediates Expenditure incurred on capital works shall be capitalised.

XII. Depreciation

(a) Adequate records shall be maintained showing the values and other particulars of fixed assets in respect of which depreciation is to be provided. These records shall inter-alia indicate the cost of each item of asset, the date of its acquisition, and the rate of depreciation. In respect of those assets, the original cost of acquisition of which cannot be ascertained without an unreasonable expenditure or delay, the valuation as shown in the books on the first day of the financial year beginning on or after the commencement of these rules shall be taken as the opening balance.

(b) The basis on which depreciation is calculated and further allocated to the various departments, cost centres and to the products shall be clearly indicated in the records. Depreciation chargeable to the different departments, manufacturing units or cost centres shall not be less than the amount of depreciation chargeable in accordance with the provisions of sub-section (2) of Section 205 of the Companies Act 1956 and shall relate to plant, machinery and other fixed assets utilised in such departments or units or cost centres. It in case the amount of depreciation charged in the cost records is higher than the amount of depreciation chargeable under the aforesaid provisions of the Companies Act. 1956, the amount so charged in excess shall be indicated clearly in the records. However, the cumulative depreciation charged against individual assets over a period of years shall not exceed the original cost of the respective assets. The method once adopted shall be applied consistently.

XIII. Overhead expenses

(a) Adequate records showing the details of the amounts comprising the overhead expenses including the break-up of head office expenses and the data relating to apportionment of overhead expenses to he various departments or manufacturing units or cost centres shall be maintained after reconciling all such expenses with the financial accounts. Overheads relating to works, administration, selling and distribution shall be recorded separately with details. In respect of capital jobs, appropriate share of overhead expenses shall be allocated to the capital heads.

Works overheads shall include among other items, indirect materials consumed and the relevant share of staff and labour welfare expenses. The detailed break-up of the items, constituting Head Office or common unit expenses and their allocation shall be maintained indicating the basis on which they are allocated to different activities or products of the company to enable determination of an equitable charge to .the different bulk drugs and/or intermediates. The amount allocated to the different bulk drugs or intermediates shall be reasonable and appropriate. The method of apportioning overhead expenses to the various departments or manufacturing units or cost centres shall be dearly indicated in the cost records and applied consistently. Where the overhead expenses are recovered through the output of the various departments or manufacturing units or cost centres otherwise than at actuals, the method of reconciling such expenses with the actuals for the relevant period, the variances, if any and the method followed for adjusting the cost variances in determining the cost of bulk drugs shall be indicated in the cost records.

(b) Details of selling and distribution expenses and the share thereof applicable to the bulk drugs and as between different size of packs shall be maintained in such a manner so as to enable the relevant particulars to be furnished in Proforma 'C' of Schedule II. Selling and distribution expenses shall be charged only to the quantity of bulk drugs

and/or intermediates sold, if applicable. The basis of apportionment of these expenses to the bulk drugs and/or intermediates and others shall be indicated in the cost records and applied consistently.

Records showing the expenses incurred on export of bulk drugs, and/or any, shall be separately maintained so that the cost of sales within the country, and for exports can be correctly determined. These export expenses as well as the credits relating to drawbacks, sale of import entitlements etc., shall be shown in the relevant cost statements of drugs exported for arriving at the net cost.

XIV. Packing

Adequate records shall be maintained showing the cost of packing materials and wages and other expenses incurred in respect of different items packed. Where such expenses are not capable of being charged directly against individual items, the basis of apportioning the expenses shall be dearly indicated in the cost records and applied consistently. Detailed records of expenses incurred on export packing, if any, shall also be kept separately and exhibited in the relevant cost statements.

The records shall be kept in such a manner that the packing cost in respect of different types and sizes of packs arc available separately.

XV. Research and Development expenses

Adequate records showing the details of expenses incurred by the company for the development of existing products or new products or processes, if any, shall be maintained separately. If the Research and Development Department is also engaged in the design and development of the plant facilities, the appropriate share thereof shall be capitalised. The method of charging research and development expenses to the cost of production shall be indicated in the relevant cost records and such expenses shall be charged to bulk drug and/or intermediates on a reasonable basis.

XVI. Transfer price for bulk drugs used for captive consumption

Adequate records showing the quantity of bulk drugs consumed for captive consumption by the formulation division of the company and the quantity sold to outside parties shall be maintained. The quantity transferred to formulations shall 'be valued at cost. A similar procedure shall be followed in respect of intermediates consumed for the manufacture of bulk drugs. However, the selling price as well as the national price notified to the Central Government under paragraph 5 of the Drugs (Prices Control) Order, 1970, shall be shown by way of foot notes in the relevant cost statements indicating the basis on which the notional price has been arrived at.

XVII. Cost Statements

Cost statements showing separately the actual cost of production and marketing of bulk drugs and/or intermediates which are either partially or fully utilised for the manufacture of bulk drugs or sold by the company, shall be shown in proforma 'B' and 'C' of Schedule II or in any form an near thereto as practicable. Costs of bulk drugs and/or intermediates if exported, shall be exhibited in separate cost statement and the same excluded from the cost statements of those products sold in the internal market;

If a company follows a system of ascertaining costs on any basis other than actuals such as standard costing, the method adopted for arriving at the actual costs shown in the Proformae of Schedule II shall also be indicated in the cost records. Packing, selling and distribution expenses in respect of each size of packing shall also be maintained separately.

Proforma 'B' of Schedule II is meant to exhibit the final cost of each intermediate and/or bulk drug. Where, however, an intermediate and/or bulk drug passes through identifiable stages of process such as fermentation, crystallisation, extraction and purification as in the case of manufacture of antibiotics, cost records for such stages shall be maintained and reconciled with the data incorporated in Proforma 'B' of Schedule II.

XVIII. Work-in-progress and finished goods stock

The basis of arrived at the cost of work-in-progress and finished goods stock shall be indicated in the cost records so as to reveal the cost elements that have been taken into account in such computations. The cost elements referred to shall be related to the items shown in the Proformae of Schedule II. The method adopted shall be consistently followed. Records shall be maintained by the company in such details so as to enable it to fill up the particulars in Proforma 'D' of Schedule II.

XIX. Reconciliation of cost and financial accounts

The cost records shall be periodically reconciled with the financial books of accounts so as to ensure accuracy. Variations, if any, shall be clearly indicated and explained. The period for which such reconciliation is effected shall not exceed the period of the financial year of the company. The reconciliation shall be done in such a manner that the profitability of the product under reference can be correctly adjudged and reconciled with the overall profits of the company from all its activities.

A statement showing the total expenses incurred by the company indicating the share applicable to bulk drugs and/or intermediates shall be maintained in Proforma 'E' of Schedule II and reconciled with the financial accounts.

XX. Records for Stock verification

Records of physical stock verification shall be maintained in respect of all materials including different solvents, raw materials, packing materials, consumables stores, small tools and machinery spares and other finished goods stock. Records of consumption and production shall also be reconciled with the excise returns. Any losses or surpluses arising out of such verification or losses in storage or in transit shall also be indicated separately stating the method of their treatment in cost records.

XXI. Statistical statements and other records

Statistical statements and other records shall be maintained in such details so as to enable the company to comply with the requirements of this Schedule and Schedule II and to enable to cost auditor to report to the Company Law Board on all the points referred to in the Cost Audit (Report) Rules, 1968, as amended from time to time. Data relating to batchwise production, standard and actual yields, operational efficiency of individual departments occupancy and usage as well as details of major repairs and maintenance carried out shall also be maintained. Such records as will enable to identify, as far as possible, the capital employed separately *for* the bulk drugs and/or intermediates activity shall also be kept. The data shall also reveal fresh investments on fixed assets that have not contributed to the production during the year. The broad effect of under utilisation of capacity, if any, on the cost of production of the bulk drug and/or intermediates shall also be made available in the records.

SCHEDULE II
(See Rule 4)

Proforma A

Name of the Company…….

Statement showing the cost of production of self-manufactured ingredient/ substance used in the manufacture of***…….. produced during the year……

	Current Year	Previous Year
Licensed capacity of the plant……		
Installed capacity of the plant ……		

	Current Year	Previous Year
Name of the self-manufactured ingredient/substance		
Batch size		
No. of batches produced		
Gross inputs		
Output		
Yield%		
Standard Yield%*		

***Name of the bulk drug and/ or intermediate to be inserted.
*Yield % may be indicated with reference to principal raw material/intermediate.

Particulars				Per Unit							
	Qty.	Rate	Amount	Current Year				Previous Year			
				Standard		Actual		Standard		Actual	
1	2	3	4	5		6		7		8	
		Rs.	Rs.	Qty.	Cost Rs.	Qty.	Cost Rs.	Qty.	Cost Rs.	Qty.	Cost Rs.
1. Raw Materials (Each item to be specified) 2. Chemicals 3. Direct Wages 4. Service: (a) Power (b) Water (c) Steam (d) Brine (e) Chilled Water (f) Air (g) Other service if any in detail											

Particulars				Per Unit							
	Qty.	Rate	Amount	Current Year				Previous Year			
				Standard		Actual		Standard		Actual	
1	2	3	4	5		6		7		8	
		Rs.	Rs.	Qty.	Cost Rs.	Qty.	Cost Rs.	Qty.	Cost Rs.	Qty.	Cost Rs.
5. Other Works Overheads 6. Repairs & Maintenance 7. Royalty 8. Quality Control 9. Research and Development 10. Depreciation 11. Administra tive Overheads											
Total:	———	———	———	———	———	———	———	———	———	———	———
Less:		———	———	———	———	———	———	———	——	———	———
(1) Realisable value of by-products											
(2) Other credits, if any											
12. Adjustments for the difference in the value of opening and closing work-in-progress											
13. Cost of production											
14. Stock Adjustments											
Add: Opening Stock											
Less: Closing Stock											
15. Cost of self-manufactured ingredient/ substance transferred to Proforma ‘B’ for the manufacture of intermediate/ bulk drug or sold.											
16. Average sales realisation, if sold											

Notes:

1. Separate cost sheets shall be maintained in respect of each ingredient manufactured and used in the manufacture of bulk drugs/ intermediates used for the manufacture of bulk drugs.
2. The basis on which realisable value is determined for the by-products shall be clearly indicated in the cost records.
3. Abnormal losses, if any, shall be indicated both in quantity and cost in a separate statement.

4. Reason for variances between standards and actuals shall be clearly recorded. Circumstances relating to revision of standards, if any, shall also be furnished in the form of a foot-note
5. The apportionment of common overheads to the product in the case of multi-product units shall be equitable vide para XIII of Schedule I
6. Where composite machine hour rates are applied, proper supporting records indicating the equipment usage in the case of multipurpose plants shall be maintained. The variances arising out of the predetermined rates shall be adjusted to arrive at the actual cost at the end of the year.
7. Details of raw materials are to be indicated under item I- raw materials.
8. If part of product is sold, details of the quantity, price and value thereof shall be shown in the records.
9. Bonus to employees other than incentive bonus shall be excluded and exhibited only in Proforma 'C'.
10. Where standard costing is not followed, column relating to 'Standard' need not be filled in.

Proforma B

Name of the Company ……
Statement showing the cost of……. Ingredient/final bulk drug
Manufactured of during the year……

Conversion of ……..into……..

	Current Year	Previous Year
1. Capacity of the plant:		
Licensed:		
Installed:		
2. Batch size		
3. No. of batches produced		
4. Gross inputs		
5. Recoveries, if any		
6. Output		
7. Yield%*		
8. Standard Yield%		

*Yield % may be indicated with reference to principal raw material/intermediate.

Particulars	Qty.	Rate	Amount	Per Unit				% Variation from standard	
				Current Year		Previous Year			
				Standard	Actual	Standard	Actual	Current Year	Previous Year
1	2	3	4	5	6	7	8	9	10
1. Raw Materials (a) Purchased (Each item to be specified) (b) Intermediates (Each item to be specified) (c) Raw materials covered by proforma 'A' (d) Other Conversion Materials & Chemicals 2. Direct Wages 3. Service: (i) Power (ii) Water (iii) Steam (iv) Brine (v) Chilled Water (vi) Air (vii) Other service, if any in detail									

Particulars	Qty.	Rate	Amount	Per Unit				% Variation from standard	
				Current Year		Previous Year			
				Standard	Actual	Standard	Actual	Current Year	Previous Year
1	2	3	4	5	6	7	8	9	10
4. Other works Overheads 5. Repairs & Maintenance 6. Royalty 7. Quality Control 8. Research & Development 9. Depreciation 10. Administration overheads Total Less: (1) Realisable value of by-products (2) Other credits, if any 11. Adjustment for difference in the value of opening and closing working progress 12. Cost of production of bulk drug/ intermediate									

Notes:

1. Separate cost statements shall be kept in respect of each bulk drug and each intermediate manufacture.
2. The basis on which the reliasable value is determined for the by-products shall be clearly indicated in the cost records.
3. Abnormal losses, if any, both in quantity and cost shall be shown in a separate statement indicating the reasons therefore.
4. Where composite machine hour rates are applied, proper records relating to the utilisation of labour and multi-purpose plants for different processes/products shall be kept to enable determination of total machine hour cost chargeable to the particular bulk drug/ intermediate. The variances in this regard shall be adjusted to arrive at the actual cost of production at the end of the year.
5. The apportionment of common overheads to the product in the case of multi-product units shall be equitable vide para XIII of Schedule I.
6. Details of raw materials are to be indicated under item I- raw materials.
7. Intermediate transferred from one process to the next process shall be at actual cost.
8. Reason for variances between standards and actuals shall be clearly recorded. Circumstances relating to revision of standards, if any, shall also be furnished in the form of a foot-note.
9. If any intermediates are sold, details of the quantity, price and value thereof shall be shown in the records.
10. Bonus to employees other than incentive bonus shall be excluded and exhibited only in Proforma ‘C’ under the heading “other expenses not included in cost.
11. Where standard costing is not followed, column relating to ‘Standard’ need not be filled in.

Proforma C

Name of the Company ……

Statement showing cost of sales of packed**…….

Produced and sold/consumed during the year……

	Current Year	Previous Year
1. Quantity produced		
2. Quantity used for captive consumption by the company		
3. Quantity packed		
4. Quantity sold in the country		
5. Quantity exported		
6. Sizes of packing		

**Name of the bulk drug intermediate to be shown here.

Particulars	Quantity	Rate per unit Rs.	Total Cost Rs.	Cost per unit	
				Current Year Rs.	Previous year Rs.
1	2	3	4	5	6
1. Cost of naked bulk drug/ intermediate as per Proforma 'B'					
2. Packing Cost:					
(a) Non-returnable containers					
(b) Other packing materials					
(c) Wages					
(d) Overheads					
3. Total cost of packed bulk drug/ intermediate					
4. Add: Opening Stock					
5. Less: Closing Stock					
Net ex-works cost of packed Product sold/ consumed during the year					
6. Selling & Distribution expenses (For quantities sold only):					
(a) Salaries & Wages					
(b) Publicity					
(c) Depot Expenses					
(d) Freight					
(e) Handling charges					
(f) (i) Commission under D.P.C. Order, 1970					
(ii) Extra Commission, paid, if any.					
(g) Discounts					
(h) Others					
Total selling & distribution expenses					

Particulars	Quantity	Rate per unit Rs.	Total Cost Rs.	Cost per unit	
				Current Year Rs.	Previous year Rs.
1	2	3	4	5	6
7. Total cost including selling & distribution expenses 8. Interest charges 9. Other expenses not included in cost (details to be listed) 10. Total expenses including interest and other charges and excluding excise duty 11. Total expenses in respect of quantities sold in the country excluding excise duty and export expenses 12. *Average sales realisation (excluding excise duty) for quantities sold in the country 13. Margin on the sales within the country. Total of 12(-) 11.					

Notes:

1. Separate cost statements shall be maintained in respect of each bulk drug intermediate and for each size of pack.
2. The apportionment of common selling and distribution expenses to the product in the case of multi-product units shall be equitable vide para XIII of Schedule 1.
3. All Bonus to employees other than incentive bonus shall be shown only in this Proforma 'C' under item 9 – "other expenses" and not in any other Proforma.
4. Detailed records for the total selling and distribution expenses shall be maintained and only the appropriate share allocable to the bulk drugs and/or intermediates is to be charged indicating in the records the basis adopted for this allocation.
5. All interest charges on self-manufactured ingredients, intermediates and bulk drugs shall be shown in Proforma 'C' only and not in any other Proforma.
6. *Average sales realisation shall be indicated separately for quantities sold at (i) price notified by the Central Government under Drugs (prices Control) Order 1970 and / or (ii) at prices fixed by the company.
7. Separate cost statements shall be prepared for intermediates and bulk drugs exported.
8. Reason for any major variations between actuals for the current and the previous year shall be clearly recorded.

Proforma D

Name of the Company ……

I. Statement showing the value of work-in-progress at the end of the year……

Particulars	Rs.
1. Opening work-in-progress as on …….	
2. Add: Expenses relating to production of bulk drugs and/or (Including items covered by Proforma 'A' of Schedule II) Incurred during the year	_____
Total……	_____
3. Less: Cost of production of bulk drugs (including items referred to in Proforma 'A' of Schedule II)	_____
4. Closing work-in-progress on…….	_____

II. Statement showing the finished stock of bulk drugs, intermediates, self-manufactured ingredients/ substance.

Type of Production	Opening Stock as on		Production during the yr.		Sold during the year		Captive Consumption		Physical stock adjust-ment, if any		Closing stock as	
	Qty. Tonne	Cost Rs.	Qty. Tonnes	Cost Rs.	Qty. Tonnes	Cost Rs.	Qty. Tonne	Cost Rs.	Qty. Tonnes	Cost Rs.	Qty. Tonne	Cost Rs.
1. Self-manufactured ingredients/ substance vide Proforma 'A' of Schedule II												
2. Intermediates: (i) (ii) (iii)												
3. Bulk Drugs: (i) (ii) (iii)												
Total:												

Proforma E

Name of the Company ……

Statement showing the total expenses incurred during the year……..
And share applicable to bulk drugs and/or intermediates.

Particulars	Total Expenses for the year Rs.	Share applicable to self-manufactured ingredients intermediates and bulk drugs Rs.	Others Rs.
1. Raw materials consumed			
2. Chemicals			
3. Other materials consumed			
4. Direct Wages			
5. Services			
6. Other Works Overheads			
7. Repairs & Maintenance			
8. Royalty			
9. Research & Development			
10. Depreciation			
11. Administration Overheads			
12. Selling & Distribution Overheads			
13. Packing materials consumed			
14. Interest charges			
15. Annual bonus to employees			
16. Other expenses, if any			
Total			
Less: (1) Realisable value of the By-products			
(2) Other credits, if any			
Total			
17. Adjustments for captive consumption of bulk drugs			
Total			
18. Adjustment for the difference between the opening and closing stock balance of			
(i) work-in-progress			
(ii) Finished stocks			
**Total (excluding excise duty)			
19* Sales realisation for quantities sold			
20. Profit			

**To be reconciled with the financial accounts for the relevant period.

*To be indicated separately for quantities of bulk drugs/ intermediates sold (i) at prices notified by Central Government under the Drugs (Prices Control) Order, 1970, (ii) at prices notified to the Government under Paragraph 5 of the Drugs (Prices Control) Order, 1970 and/or (iii) at prices fixed by the company.

[SCHEDULE III

[See rule 4(2A)]

1. **MATERIALS:**

(1) The proper records shall be maintained showing separately all receipts, issues and balances both in quantities and cost of each item of raw material (including all direct charges up to works in respect of major raw materials) required for the production of Bulk Drugs. The basis on which said quantities and costs of issue and consumption have been calculated shall be indicated in the cost records and followed consistently. In the case of imported raw materials proper records shall be maintained showing FOB value, overseas freight, insurance, customs duty and inland freight charges. If both indigenous and imported materials are consumed, the records showing details of percentage mix of the same have to be maintained for each item. In the case of imported raw material proper records shall be maintained showing license-wise allowed quantities, actual quantities imported, actual quantities consumed, quantities in stock and quantities yet to be imported out of total licensed quantities.

(2) The proper records shall be maintained separately showing the receipts, issues and balances both in quantities and cost of each item of process material or chemicals such as herbal extracts or powder, caustic soda, activated carbon and benzene used in the manufacture of the products under reference and solvents like acetone, alcohol, methanol used for processing. The cost shall include all direct charges up to works.

(3) Where basic raw materials or ingredients are produced or farm products/ herbs raised by the company, separate records showing the cost of production of each such material indicating the break up of material consumed shall be maintained to determine the cost of material produced. The basis on which the quantities and costs of issues and consumption of such materials or products produced/raised by the company are calculated shall be indicated in the cost records and followed consistently.

(4) The issues, consumption of production materials shall be identified with the batch of production, departments, and cost centre.

(5) The proper records shall be maintained indicating the quantity as well as value of by-products recovered in different processes having significant value in relation to cost of materials. In the case of certain by-products recovered, which cannot be reused in the process and are sold or disposed of without further processing, the realisation from such sales shall be recorded and adjusted against the process concerned. In case further processing is necessary to make the by-products usable or saleable, as the case may be, adequate records of the cost involved for such further processing shall be maintained. If such processing is done by any outside agency, proper records to show the quantity sent for processing, quantity received back after processing and. the cost incurred thereon shall be maintained in detail. The net realisation, if any shall be adjusted against the major process relating' to such by-product. The cost of by products shall be determined on equitable and reasonable basis and applied consistently. The records indicating the actual sales realisation of by-products shall also be maintained. Similar procedure shall be followed in the case of joint products/by products obtained in respect of other systems of medicines also.

(6) The proper records shall be maintained to show the receipts, issues and balances, both in quantities and cost of each item of consumable stores, other chemicals and extracts and powders not covered by sub-rule (2), tools and machinery spares. The cost shall include all direct charges up to works.

(7) In the case of consumable stores and small tools the *cost* of which are insignificant, the company may, if it so desires, maintain such records for the group of such consumable stores and tools.

(8) The cost of consumption of consumable stores, small tools and machinery spares shall be charged to the relevant cost centre/department on the basis of actual issues.

(9) The proper records shall be maintained showing the quantity and value of wastage, spoilage, rejections and losses of raw materials, process materials, consumable stores whether in transit, storage, manufacture or at any other stage. The method followed for adjusting the above losses as well as the income derived from the disposal of rejected and waste materials including spoilage, if any, in determining the cost of product shall be indicated in the cost records. Any abnormal wastage or spoilage or rejection shall be indicated distinctly and separately along with reasons thereof.

(10) The proper records shall also be maintained to indicate the value of raw materials and components, finished and semi-finished, which have not moved for more than twelve months.

(11) Where any credit under Central Value Added Tax (CENVAT) or any other benefits of the nature of CENVAT Credit under the Central Excise Act, 1944 (1 of 1944) are available on any item of material, the cost of such material should be shown after adjusting such credit or benefits.

(12) If any of the materials purchased is processed by an outside party proper records shall be maintained for the quantity sent for processing, quantity received after processing, by products received, if any, and the Cost involved in processing.

2. SALARIES AND WAGES:

(1) The proper records shall be maintained to show the attendance and earnings of all employees of the cost centres or departments and the work on which they are employed. The records shall also indicate the following separately for each cost centre or development.

(a) piece rate wages (Wherever applicable);
(b) incentive wages, either individually or collectively as production bonus or under any other scheme based on output;
(c) overtime wages;
(d) earnings of casual /contractual labour;
(e) bonus or gratuity, statutory as well as others;
(f) contribution to superannuating scheme;
(g) any other earning of similar nature.

(2) The records shall be maintained in such a manner as to enable the company to furnish necessary particulars under this head in Proformae A, B, C and D of Schedule III annexed to these rules. The records may be maintained to book these expenses cost centre-wise or department-wise with reference to activities related to the production of Bulk Drugs. Where the employees work in such a manner that it is not possible to identify them with any cost centre or department, the labour charges shall be apportioned to the cost centres or departments on equitable and reasonable basis and applied consistently.

(3) The idle labour cost shall be separately recorded under classified headings indicating the reasons therefore. The method of accounting followed for accounting of idle time payments shall be disclosed in the cost records. '

(4) Any wages and salaries allocable, to capital works such as additions to plant and machinery, buildings or other fixed assets shall be accounted for under the relevant capital heads. Similarly payments in the nature of deferred revenue expenditure separately recorded under separate classified headings indicating the reasons therefor. The method followed for accounting of such payments in determining the cost of the product shall on equitable and reasonable basis and applied consistently. The said method shall be disclosed in the cost records also. .

(5) Only such retirement costs, which are likely to provide benefits in terms of savings in cost in future shall be treated as deferred revenue expenditure. This amount shall be treated as extraordinary item. Therefore these

expenses shall not form part of salary and wages and shall be shown separately as an abnormal item of expense. Similarly excess of termination benefits for the past period payable over and above the provision made in this regard shall also be treated as abnormal item of expense. The expenses on account of any voluntary retirement scheme shall be excluded from valuation of inventories also for that period as these expenses do not result in putting the inventories to their present location and condition.

3. SERVICE DEPARTMENT EXPENSES:

The detailed records shall be maintained to indicate expenses incurred in respect of each service department or cost centre like laboratory, welfare, transport etc. These expenses shall be apportioned to other services and production departments on equitable and reasonable basis and applied consistently. Where these services are utilised for other products of the company also, the basis of apportionment of such expenses to any type of Bulk Drugs and to the other products shall be on equitable and reasonable basis and applied consistently.

4. UTILITIES:

(1) Water: -The proper records showing the quantity and cost of treated, or chilled or raw or soft or demineralised water or brine produced and consumed, if any, for the manufacture of any type of Bulk Drugs in different cost centres or departments shall be maintained. The cost of treated or cooling water, consumed by Bulk Drugs plant and other units of the company shall be apportioned to respective units on equitable and reasonable basis and applied consistently.

(2) Steam: - Where steam is raised by the company, proper records showing the quantity and cost of steam raised and consumed for the manufacture of the Bulk Drugs shall be maintained. The cost of steam consumed by the Bulk Drugs units and by other units of the company shall be apportioned on equitable and reasonable basis and applied consistently. Where steam is raised and supplied by any other unit of the company to the Bulk Drugs plant, the cost of steam so supplied shall be charged to the Bulk Drugs Plant on actual cost basis.

(3) Power: -Where power is purchased, proper records shall be maintained for the units and cost of power consumed for the production of Bulk Drugs in different cost centres or departments. Where power is generated by the company itself, adequate records, showing all elements of cost shall be maintained to show the cost of power generated and consumed for the production of the Bulk Drugs in different cost centres or departments. Records shall also indicate installed capacity, number of units generated losses and consumption -in each cost centres or departments separately. Where power is generated and supplied by any other unit of the company to the Bulk Drugs plant, adequate records shall be maintained to indicate the quantity and cost of power so supplied. The cost of power consumed by the Bulk Drugs units and by other units of the company shall be apportioned on equitable and reasonable basis and applied consistently. The records shall state clearly the measures taken on conservation of energy and its corresponding impact on per unit cost of production.

(4) Air-conditioning: - The proper records shall be prepared to enable determination of the cost of air-conditioning and its distribution cost centre-wise or department-wise. The cost of air conditioning shall be apportioned to Bulk Drugs on equitable and reasonable basis and applied consistently.

(5) Other Utilities: - The proper records showing quantity and cost shall be maintained in respect of any other utilities produced or purchased by the company for the production or manufacture of Bulk Drugs.

(6) The cost statements for each utility shall be maintained separately in Proforma A.

5. WORKSHOP OR REPAIRS AND MAINTENANCE OR TOOL ROOMS:

(1) The proper records showing the expenditure incurred by the workshop or tool room under different heads and on repairs and maintenance in the various cost centres or departments shall be maintained. The records shall also indicate the basis of charging the workshop or repairs and maintenance or tool rooms expenses to different cost centers or departments. Where maintenance work is done by direct workers of any production cost centre or department,. the wages and salaries of such workers shall be treated as direct expenses of the respective cost centre or department. If the services are utilised for other products also, the manner of charging a share of the cost of

workshop or repairs and maintenance or tool room expense, to such products shall be on equitable and reasonable basis and applied consistently.

(2) ln addition to the above, records shall indicate the amount and also the proportion of closing inventory of stores and spare parts representing items which have not moved for over twenty four months.

(3) The expenditure on major repair works from which benefit is likely to accrue for more than one financial year shall be allocated over the period expected to benefit on equitable and reasonable basis and applied consistently. Such costs shall be shown separately and method of accounting and the basis of the allocation of such costs shall also be clearly indicated in cost records.

6. DEPRECIATION:

Depreciation shall be allocated/ apportioned to various cost centres or departments and absorbed on all products on equitable and reasonable basis and applied consistently which shall be clearly indicated in the cost records. If depreciation charged or chargeable to the cost centres or departments is in excess or lower than the depreciation calculated by applying the rates of depreciation prescribed under the provisions of sub-section (2) of Section 205 of the Companies Act, 1956 (1 of 1956), such amount of excess or lower depreciation shall be indicated clearly in the cost records. The cost records shall also show the effect of such excess or lower depreciation as the case may be, on the per unit cost of Bulk Drugs. The cumulative depreciation charged in the cost records, against any individual item of asset shall not, however, exceed the original cost of the respective asset.

7. OTHER OVERHEADS:

(1) The proper records shall be maintained for the product under reference showing the various items of expenses comprising the other overheads. These expenses shall be analysed, classified and grouped according to functions, namely, works, administration, selling and distribution.

(2) Where the company is manufacturing products other than the Bulk Drugs, the records shall clearly indicate the basis followed for apportionment of the common overheads including head office expenses of the company to such products and Bulk Drugs, including capital works. Where certain expenses forming part of overheads can be identified with a particular activity or a product, such expenses shall be first segregated and charged to the relevant activity or product and thereafter the residual expenses under the above categories of overheads shall be apportioned on equitable and reasonable basis and applied consistently. Overheads chargeable to capital works shall be indicated separately in the cost records. The basis of apportionment or absorption of overheads to the cost centres or departments and products shall be indicated in the cost records. The records shall be maintained in such a manner as to indicate the details of works, administration, selling and distribution overheads.

8. ROYALTY/ TECHNICAL KNOW-HOW FEE:

The adequate records shall be maintained showing the royalty and/or technical knowhow fee including other recurring or non-recurring payments of similar nature, if any, made for the product under reference to collaborators or technology suppliers in terms of agreements entered into with them. Such records shall be kept separately in respect of each such collaborator or supplier. The basis of charging such royalty amount, including lump sum payment, to the products shall be at the point of incidence in accordance with the royalty agreement and shall be indicated in the cost records.

9. RESEARCH AND DEVELOPMENT EXPENSES:

(1) The proper records showing the details of expenses, if any, incurred by the company for the research and

development work on the product covered under these rules according to the nature of development of products, existing and new products and processes, development of process of manufacture, existing and new, design and development of new plant facilities and market research for the existing and new products, shall be maintained separately.

(2) The method of charging these expenses to the cost of Bulk Drugs and other products shall be indicated in the cost records. Where the utility of such research and development work extends over more than one financial year, such expenses shall be treated as deferred expenses and charged to the cost of production of the Bulk Drugs and other products if any, on equitable and reasonable basis and applied consistently. The following criteria which are only indicative and not exhaustive may be adopted in such cases:

(i) The product or process is clearly defined and the costs attributable to the product or process can be separately identified.
(ii)The technical feasibility of the product or process has been demonstrated.
(iii)The management of the enterprise has indicated its intention to produce and market, or use, the product or process.
(iv)There is a reasonable indication that current and future research and development costs to be incurred on the project together with expected production, selling and distribution costs are likely to be more than covered by related future revenues/benefits; and
(v)Adequate resources exist, or are reasonably expected to be available, to complete the project and market the product or process.

(3) The expenses incurred by the Research and Development Department for providing technical know-how to outsiders shall be recorded separately and excluded from the cost of Bulk Drugs. The amount recovered for providing technical know-how to outsiders shall also be indicated separately and excluded from the income arising from the sale of Bulk Drugs.

10. QUALITY CONTROL:

The adequate records shall be maintained to indicate the expenses incurred in respect of quality control department or cost centre for product under reference. Where these services are also utilised for other products of the company, the basis of apportionment to Bulk Drugs and to other products shall be on equitable and reasonable basis and applied consistently.

11. INTEREST:

The proper records shall be maintained 'for interest charges paid. The amount of interest shall be allocated or apportioned to the products covered by these rules and other activities on equitable and reasonable basis and applied consistently. The basis of further charging of the share of the interest to the various types of such products shall also be equitable and reasonable and applied consistently. The basis of such allocation or apportionment shall be spelt out clearly in the cost records or statements.

12. EXPENSES OR INCENTIVES ON EXPORTS:

The proper records showing the expenses incurred on the export sales, if any, of the product under reference shall be separately maintained so that the cost of export sales can be determined correctly. Separate cost statement shall be prepared for Bulk Drugs exported giving details of export expenses incurred or incentive earned. In case, duty free imports are made, the cost statements should reflect this fact. If the duty free imports have been made after actual production, the statement should reflect this fact also.

13. PACKING EXPENSES:

(1) The proper records shall be maintained showing the quantity and cost of various packing materials and other expenses incurred on packing for marketing of the Bulk Drugs. If such expenses are incurred in common for Bulk Drugs and other products, these expenses shall be apportioned to relevant products on equitable and reasonable basis and applied consistently.

(2) The detailed records of the expenses incurred on export packing, if any. Shall also be kept separately and exhibited in the relevant cost statements for exports.

14. WORK IN PROGRESS AND FINISHED STOCK:

The method followed for determining the cost of work in progress and finished stock of the Bulk Drugs shall be indicated in the cost records so as to reveal the cost element that have been taken into account in such computation. All conversion costs incurred in bringing the inventories to their present location and condition shall be taken into account while computing the cost of work in progress. The method adopted for determining the cost of work in progress and finished goods shall be followed consistently.

15. COST STATEMENTS:

(1) The cost statement showing details of installed capacity, production, wastage, issues and sales and all elements of cost of the current financial year and previous year shall be prepared for each process adopted in manufacture or production of Bulk Drugs in Proformae A, B,C and D.

(2) The product emerging from a process which forms raw material or an input material for a subsequent process shall be valued at the cost of production up to the previous stage.

(3) If the company is operating more than one plant or factory, separate cost statements as specified above shall be prepared in respect of each plant or factory.

16. PRODUCTION RECORDS:

Quantitative records of all finished goods, whether packed or unpacked showing production, issues' for sales and balances of different type of the products under reference produced by the company shall be maintained.

17. RECONCILIATION OF COST AND FINANCIAL ACCOUNTS:

(1) The cost statements shall be reconciled with the financial statements for the financial year specifically indicating the expenses or incomes not considered in the cost records or statements so as to ensure accuracy and to adjudge the profit of the product under reference with the overall profit of the company. The variations, if any, shall be clearly indicated and explained.

(2) A statement showing the total expenses incurred and income received by the company under different heads of accounts and the share applicable to other products and the products under reference shall be prepared and reconciled with the financial statement.

18. ADJUSTMENT OF COST VARIANCES:

Where the company maintains cost records on any basis other than actual such as standard costing, the records shall indicate the procedure followed by the company In working out the cost of the product under such system. The cost variances shall be shown against the separate heads and analysed into material, labour, overheads and further segregated into quantity, price and efficiency variances. The method followed for adjusting the cost variances in

determining the actual cost of the product shall be indicated clearly in the cost records. The reasons for the variances shall be duly explained in the cost records or statements.

19. STATISTICAL RECORDS:

(1) The records regarding available machine hours or direct labour hours in different production departments and actually utilised shall be maintained for production of product under reference and shortfall suitably analysed. Suitable records for computation of idle time of machines shall also be maintained and analysed.

(2) The adequate records shall be maintained to enable the company to identify the capital employed, net fixed assets and working capital separately for the production or manufacture of product under reference and other products and other activities. Fresh investments of fixed assets for production of Bulk Drugs that have not contributed to the production during the year shall be disclosed separately in the cost records. The records shall, in addition, show assets added as replacement and those added for increasing existing capacity. Also such records as will enable identification and/or allocate gross fixed assets, accumulated depreciation up to the year, net fixed assets under the heads; Land & Buildings, Plant & Machinery, Furniture & Fixture etc. employed for the production of Bulk Drugs, along with the method and rate of depreciation shall be maintained. The basis of apportionment of common assets to the products(s)under reference shall also be indicated. In case of revaluation of assets, the same should be indicated separately. The basis of allocati9n of indirect assets to the respective bulk drugs should be reasonable, equitable and shall be followed consistently.

(3) Whenever WTO provisions are attracted, proper records shall be maintained to identify the competitiveness of the product in the domestic as well as global market and the expenses, if any, incurred to combat the competition arising out of WTO provisions. Adequate statistical records shall also be maintained to identify the market share of the product manufactured and the likely impact thereon on account of competitive goods imported in to the country. These records shall indicate, inter alia, the total volume of imports, names of importers countries of origin and contain such empirical evidence as to show whether such imports can be construed as _dumping and affecting the market share of the product. Proper records shall also be maintained, containing such details as may be necessary to show that the export price of the product is not such as to be construed as dumping in the importing country, by applying the provisions of WTO regarding anti dumping measures under Article VI of GATT 94. .

20. CAPTIVE CONSUMPTION:

If Bulk Drugs are used for captive consumption by the formulation division, proper records shall be maintained showing the quantity and cost of each item of Bulk Drugs transferred to other departments or units of the company for self-consumption and sold to outside parties. The rates at which the transfers are affected shall be at cost only. A similar procedure shall be followed in respect of intermediates consumed for the manufacture of Bulk Drugs. However, in the case of allopathic system of medicines, the selling price as well as the notional price notified by the Central Government under the Drugs (Prices Control) order, 1995 shall be shown by way of footnotes in the relevant cost statements indicating the basis on which the notional price has been arrived at.

21. POLLUTION CONTROL:

Expenditure incurred by the company on various measures to protect the environment like effluent treatment, control of pollution of air, water, etc., should be properly recorded.

22. HUMAN RESOURCES DEVELOPMENT:

Expenditure incurred by the company on the human resources development activity shall be recorded separately.

23. INTER-COMPANY TRANSACTIONS:

(1) In respect of related party transactions or supplies made or services rendered by a company to its holding company or subsidiary or a company termed "related party relationship" as defined below and vice-a--versa, records shall be maintained showing contracts entered into, agreements or understanding reached in respect of:

(a) Purchase and sale of raw materials, finished products, process materials, chemicals and rejected goods including scraps, etc;

(b) Utilization of plant facilities and technical know-how;

(c) Supply of utilities and any other services;

(d) Administrative, technical, managerial or any other consultancy services; (e) purchase and sale of capital goods including plant and machinery;

(f) Any other payment related to production, processing or manufacturing of product under reference. These records shall also indicate the basis followed for arriving at the rates charged or paid for such products or services so as to enable determination of the reasonableness of such rates in so far as they are in any way related to product under reference.

(2) The transactions by the following "related party relationships" shall be covered under sub-rule (1):

(a) Enterprises that directly, or indirectly through one or more intermediaries, control, or are controlled by, of are under common control with, the reporting enterprise (this includes holding companies, subsidiaries and fellow subsidiaries);

(b) Associates and joint ventures of the reporting enterprise and the investing party or venture in respect of which the reporting enterprise is an associate or a joint venture;

(c) Individuals owning, directly or indirectly, an interest in the voting power of the reporting enterprise that gives them control or significant influence over the enterprise, and relatives of any such individual;

(d) Key management personnel and relatives of such personnel; and

(e) Enterprises over which any person described in (c) or (d) is able to exercise significant influence. This includes enterprises owned by directors or major shareholders of the reporting enterprise and enterprises that have a member of key management in common with the reporting enterprise.

However, the following shall not be deemed as "related party relationships":

(a) Two companies simply because they have a Director in common, notwithstanding paragraph (d) or (e) above (Unless the Director is able to affect the policies of both companies in their mutual dealings);

(b) A single customer, supplier, franchiser, distributor, or general agent with whom an enterprise transacts a significant volume of business merely by virtue of the resulting economic dependence; and

(c) The parties listed below, in the course of their normal dealings with an enterprise by virtue only of those dealings (although they may circumscribe the freedom of action of the enterprise or participate in its decision making process);

(i) Providers of finance;
(ii) Trade unions;

(iii) Public utilities;

(iv) Government departments and government agencies including government sponsored bodies.

Explanation: -For the purpose of these Rules,

(a) "Related party relationship" mean parties who are considered to be related if at any time during the reporting period one party has the ability to control the other party or exercise significant influence over the other party in making financial and/or operating decisions;

(b) "Related party transaction," means a transfer of resources or obligations between related parties, whether or not a price is charged;

(c) "Control" means

(i) Ownership, directly or indirectly, of more than one-half of the voting power of an enterprise; or

(ii) Control of the composition of the Board of Directors in the case of a company or of the composition of

the corresponding governing body in case of any other enterprise; or

(iii) a substantial interest in voting power and the power to direct, by statute or agreement, the financial and/or operating policies of the enterprise.

(d) "Significant influence" means participation in the financial or operating policy decisions of an enterprise, but not control of those policies;

(e) "Associate," means an enterprise in which an investing reporting party has significant influence and which is neither a subsidiary nor a joint venture of that party;

(f) "Joint venture" means a contractual arrangement whereby two or more parties undertake an economic activity, which is subject to joint control;

(g) "Joint Control" means the contractually agreed sharing of power to govern the financial and operating policies of an economic activity So as to obtain benefits from it;

(h) "Key management personnel" mean those persons who have the authority and responsibility for planning, directing and controlling the activities of the reporting enterprise;

(i) "Relative"-in relation to an individual, means the spouse, son, daughter, brother, sister, father and mother who may connected by blood relationship;

(j) "Holding company" means a holding company within the meaning of Section 4 of the Companies Act, 1956 (1 Of 1956);

(k) "Subsidiary" means a subsidiary company within the meaning of Section 4 of the Companies Act, 1956 (1 of 1956);

(1) "Fellow subsidiary" means a company is said to be a fellow subsidiary of another company if both are subsidiaries of the same holding company;

(m) "State-controlled enterprise" means an enterprise which is under the control of the central Government or a State Government."

24. MULTI-PURPOSE VESSELS:

When more than one manufacturing process is carried out in a particular or series of vessels, adequate records about the usage of such vessels for different products shall be kept. The cost of using such vessels shall be charged to the different products on an equitable basis such as equipment occupancy hours. Where composite machine hour rates are applied for absorption of wages, overheads and equipment usage, proper records relating to the utilization of labour and multi-purpose vessels for different processes connected with the manufacture of different products shall be kept to enable determination of total machine hours and the amounts chargeable to the respective Bulk Drugs and intermediates. The variances between the actuals and the amounts charged at pre-determined rates shall be adjusted for arriving at the actual cost of production at the end of the year.

25. Technical information:

The proper records shall be maintained to provide technical details relating to chemical process, fermentation process and manufacturing process, as indicated below.

(A) For chemical process:

(i) In the case of dedicated facilities, details such as name of the equipment and designed capacity, number of equipments available, position/code number of the equipment, reaction/operation carried out in the equipment. batch size (input/batch and output/batch), occupancy time hour, yield and WIW with respect to main input at each stage and the cumulative yield, by-product/recoveries of solvents etc. (Kg./Ltr.) shall be maintained. .

(ii) ln case any other product is manufactured in the above set of equipment similar data shall be maintained for such item and allocation of time at each equipment alongwith basis of allocation

(iii) ln both the above situations, the company need to maintain the record of actual. capacity utilization against the installed capacity along with the details of scheduled maintenance programme and the number of days spent on unscheduled maintenance of the plant during the year. Reasons for operating at lower capacity, if any, may also be recorded.

(B)For Fermentation process-
If the drug is manufactured by fermentation process the following information shall be maintained on annual average basis.
(i) Number of fermenters with their operating capacity/volume, average fermentation hours and turnaround time.

(ii) Average whole broth volume, whole broth potency and filtered broth potency per batch.
(a) Stage-wise and overall percentage recovery efficiency of both drug and intermediate from the fermented broth.
(b) Average batch output and number of batches processed and drained.
(c) Average potency/purity of the finished drug.
(d) Stage-wise annual average quantity consumption of all major raw materials including solvents usage shall be maintained along with quantity produced at each stage. Similarly details of consumption of primary utilities of in respect of the drug shall be maintained.

(C) Manufacturing Process- The manufacturing process adopted by the company along with the flow chart shall be kept. Appropriate chemical equation of reaction with molecular weight and recovery levels of solvents and by-product at each stage shall also be kept. Further, in case of any change in the process of technology and the consequential benefit there from during the year or in the recent past shall be maintained.

PROFORMA 'A'

Name of the company
Name and address of the factory

Statement showing the cost of Utility like Power, Steam, Water, Effluent treatment etc., produced and consumed during the year/period

A Quantitative Information:

Serial Number	Particulars	Current Year (unit)	Previous Year (unit)
1.	Installed capacity		
2.	Quantity produced	-	
3.	Capacity utilisation		
4.	Quantity re-circulated		
5.	Quantity purchased		
6.	Consumption in power house including other losses		
7.	Net quantity consumed		

B Cost Information:

Serial Number	Particulars	Quantity	Rate (Rupees per unit	Amount (Rupees) (in lacs)	Cost unit	Per (Rupees)
					Current Year	Previous Year
A 1.	Materials(specify) (a) (b) (c)					
2.	Utilities(specify) (a) (b) (c)					
3.	Consumable stores					
4.	Salaries and wages					
5.	Repairs and maintenance					
6.	Other overheads					
7.	Depreciation					
8.	Total					
9.	Less: Credit, if any					

10.	Net Total					
B.	Apportioned to 1. 2. 3. 4.			.		

Note 1.- Separate cost sheet is to be prepared for each utility as well as effluent treatment.

Note 2.- If any of the utilities or services, which are manufactured by the company and transferred to any other unit of the company or is sold to outside parties, separate cost sheet shall be prepared in proforma-B in respect of such sale or transfer, which shall be effected at cost of sales of respective utility.

Proforma B

Name of the company
Name and address of the factory

Statement showing the summary cost of production in respect of ……..(specify name of each type of ingredients/intermediates produced/processed/manufactured during the year/period.....

A Quantitative Information:

Serial Number	Particulars	In Metric Tonnes	
		Current Year	Previous Year
1.	Installed capacity		
2.	Batch size		
3.	Number of batches produced		
4.	Gross Inputs		
5.	Output		
6.	Yield %		
7.	Standard yield %		
8.	IEM/SSI Registration No. alongwith the date.		
9.	Date of Commissioning.		
10.	Date of Commencement of commercial production.		
11.	No. of shifts: One/Two/Three per day		
12.	No. of operating days per week		
13.	Dedicated/multipurpose equipment plant.		
14.	Quantity captively consumed		
15.	Opening stock		
16.	Closing stock		

B Cost Information:

Serial Number	Particulars	Quantity	Rate (Rs)	Amount (Rupees in lacs)	Quantity per unit (Current year and previous year)		Cost per unit (Rupees)	
					Standard	Actual	Current Year	Previous Year
1.	Material cost (item wise covering 80% of value) (a) (Specify name of raw material) (i) Imported (ii) Indigenous (iii) Own produced (b) (Specify name of raw material) (i) Imported (ii) Indigenous (iii) Own produced (c) Other Materials (specify) (d) Total Raw-Materials (a to c) (e) Less: By-products and Recoveries (f) Net cost of raw-materials (d-e)							
2.	Process Chemicals (a) Solvents (b) Extracts/oils (c) Others (specify)							
3.	Direct Wages and Salaries							
4.	Utilities (a) Power (b) Steam (c) Water (d) Air-conditioning (e) Brine (f) Chilled water (g) Effluent water treatment plant (h) Others (i) Total (a to h)							
5.	Consumable stores and spares							
6.	Depreciation							
7.	Repairs and maintenance							
8.	Royalty							
9.	Research and development							
10.	Quality control							
11.	Other Factory overheads							
12.	Administrative overhead (a) Salaries and wages (b) Others (please specify) (c) Total (a+b)							

13.	Total (1 to 12)							
14.	Less: Credits (from wastages and by-products)							
15.	Stock adjustment (work in progress)							
16.	Cost of production							
17.	Stock adjustment (finished products)							
18.	Net cost of Production							
19.	Apportioned to: 1. 2. (Specify)							

Note

1. -Separate proforma shall be prepared in respect of each type of intermediate under reference.
2. -Separate cost sheet shall be prepared in proforma C in respect of inter-company transfers referred to in para 23 of the Schedule III.
3. -Reasons for variations between standards and actuals shall be clearly recorded. Circumstances leading to revision of standards, if any shall also be indicated in the form of a foot note.
4. -The administration overheads shall be included in the cost *of* production only to the extent they contribute in putting the goods produced to their present location and condition. The balance of administration overheads, if any, shall be included in the cost Of goods sold. The Proformae may be amended accordingly, if required.
5. -If any of the intermediates produced or manufactured by the company is transferred to any other unit of the company or is sold to outside parties, separate cost sheet shall be prepared in Proforma, C in respect of such sale or transfer, which shall be effected at cost of sales of the respective product.

Proforma C

Name of the company
Name and address of the factory

Statement showing the summary cost of sales, sales realisation and margin in respect of . . . . . (specify name of each type of ingredients/intermediates/Bulk Drugs) produced/processed/manufactured and sold during the year/period.....

A Quantitative Information:

Serial Number	Particulars	In Metric Tonnes	
1.	Installed capacity	Current Year	Previous Year
2.	Batch size		
3.	Number of batches produced		
4.	Gross Inputs		
5.	Output		
6.	Yield		
7.	Standard yield %		
8.	IEM/SSI Registration No. alongwith the date		
9.	Date of Commissioning		
10.	Date of Commencement of commercial production		
11.	No. of shifts: One/Two/Three per day		
12.	No. of operating days per week		
13.	Dedicated / multipurpose equipment plant		
14.	Quantity sold (a) Domestic (b) Exports		
15	Quantity captively consumed		
16.	Opening stock (fin. Goods)		
17.	Closing stock (fin. Goods)		

B. Cost Information:

Serial Number	Particulars	Quantity	Rate (Rs.)	Amount (Rupees in lacs)	unit (Current Quantity per year/previous year)		Cost per unit (Rupees)	
					Standard	Actual	Current Year	Previous Year
1.	Material cost (item-wise covering 80% of value) (a)(Specify name of raw material) (i)imported (ii)indigenous (iii)Recovered (iv) Own manufactured (b)(Specify name of raw material) ((i)imported (ii)indigenous (iii)Recovered (iv)Own manufactured (c) Other materials (specify) (d) Total Raw Materials (a to c) (e) Less: By-Products and Recoveries (f) Net cost of raw--materials (d-e)							
2.	Process Chemicals (a) Solvents (b) Others (specify)							
3,	Direct Wages and Salaries							
4.	Utilities (a) Power (b) Steam (c) Water (d) Air-conditioning (e) brine (f)Chilled water (g) E.T.P. (h) Others							

	(i) Total (a to h)							
5.	Consumable Stores and spares							
6.	Depreciation							
7.	Repairs and maintenance							
8.	Royalty							
9.	Research and development							
10.	Quality control							
11.	Other Factory overheads							
12.	Administrative overhead (a) Salaries and wages (b) Others (please specify) (c) Total (a+b)							
13.	Total (1 to 12)							
14.	Less: Credits (from wastages and by-products)							
15.	Stock adjustment (work in progress)							
16.	Cost of production							
17.	Stock adjustment (finished products)							
18.	Net cost of Production of unpacked finished goods							
19.	Less: captive consumption (product-wise details of finished output by given)							
20.	Packing Cost (a) materials (b) others							
21.	Less: Captive Consumption in packed condition (Details be given)							
22.	Net ex-works cost of packed products.							
23.	Selling and Distribution Expenses: (a) Salaries and wages (b) Freight and Transport Charges (c) Commission to selling agents (d) Advt. Expenses (e) Royalty (f) Others (g) Total (a to f)							
24.	Cost of sales							
25.	Interest							

26.	Other expenses / incomes not included in costs (details to be given)							
27.	Total cost (excluding excise duty)							
28.	Total sales realization excluding excise duty Add: Export benefits and incentives, if any							
29.	Margin (28-27)							

Note

1.- Separate proforma shall be prepared in respect of each type of product under reference.

2.- Separate proforma shall be prepared for the quantity sold with in the country and the quantity exported. Expenses incurred on export and the incentive earned thereon shall be indicated in the proforma applicable for the quantity produced and exported.

3,- Sales realisations shall be separately indicated for the quantities of product under reference sold (i) at the notified prices under Drug (Prices Control) Order, 1995 and/or (ii) at prices fixed by the company.

4,- Separate proforma shall be prepared in this format in respect of inter company transfers referred to in para 23 of Schedule III.

5.- Reasons for variations between standards and actuals shall be clearly recorded. Circumstances leading to revision of standards, if any, shall also be indicated in the form of a foot note.

6.- The quantitative basis of apportionment of common overheads should be enclosed separately.

7.- The administration overheads shall be included in the cost of production only to the extent they contribute in putting the goods produced to their present location and condition. The balance of administration overheads, if any, shall be included in the cost of goods sold. The Proformae may be amended accordingly, if required.

Proforma D

Name of the company
Name and address of the factory

Statement showing the total production and allocation of total actual expenses and income of the company between Bulk Drugs and other activities for the year ending……..

Allocation of total expenses and income for the year ending……..

Serial Number	Particulars	Total actual expenses As per Audited Annual Accounts	Share applicable to Bulk Drugs	Share applicable to Formulation, if any	Share applicable to other activities	Basis of Allocation
1	2	3	4	5	6	7
1.	Raw-Material consumed					
2.	Process materials / Chemicals consumed					
3.	Salaries and wages					
4.	Utilities					
5.	Consumable stores and spares					
6	Depreciation					
7.	Repairs and maintenance					
8.	Royalty					
9.	Research and development					
10.	Quality control					
11.	Other Factory overheads					
12.	Administrative overhead (a) Salaries and wages (b) Others (please specify) (c) Total (a+b)					
13.	Total (1 to 12)					
14.	Less: Credits (from wastages and by-products)					
15.	Stock adjustment (work in progress)					
16.	Cost of production					
17.	Stock adjustment (finished products)					
18.	Net cost of Production of unpacked finished					

	goods					
19.	Less: captive consumption (product-wise details of finished output by given)					
20.	Packing Cost (a) materials (b) others					
21.	Less: Captive Consumption in packed condition (Details be given)					
22.	Net ex-works cost of packed products.					
23.	Selling and Distribution Expenses: (a) Salaries and wages (b) Freight and Transport Charges (c) Commission to selling agents (d) Advt. Expenses (e) Royalty (f) Others (g) Total (a to f)					
24.	Cost of sales					
25.	Interest					
26.	Other expenses / incomes not included in costs (details to be given)					
27.	Total cost (excluding excise duty)					
28.	Total sales realization excluding excise duty Add: Export benefits and incentives, if any					
29.	Margin (28-27)					

Note-

1. If in addition to Bulk Drugs of one system of medicine, Bulk Drugs of other systems of medicine like allopathic, ayurvedic, Homeopathic etc are produced/ manufactured, additional columns similar to column 4 of the proforma shall be opened in respect of each such system of medicine.

2. All items of income and expenditure in this Proforma shall be reconciled with the financial accounts for the relevant period.

3. Bonus in excess of statutory minimum, bad debts and provisions, Donations and Charities, Loss/ Gain on sale of assets, brokerage and commission, expenses not recognized by Income Tax Authorities (salary, perquisites, advertisements, entertainment etc) adjustments relating to previous years etc. to be excluded from costs.

4. The quantitative basis of apportionment of common overheads should be enclosed separately.**]** [8]

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[8]. Inserted by G.S.R. 707(E) dated 28th September 2001.

Foot Note -The principal rules were published vide G.S.R. number 130(E), dated the 14.3.1974 and subsequently amended vide-

1. GSR 789, dated 3.6.1977.
2. GSR 1275, dated 10.10.1979.
3. GSR 28(E), dated 5.1.1983.
4. GSR 505(E), dated 26.5.1984.
5. GSR 551 dated 22.7.1989.
6. GSR 311(E), dated 24.3.1993.
7. GSR 437(E), dated 3.8.1998.
8. GSR 707(E), dated 28.9.2001.